

# Extra INSTAND EQA Scheme (340) - April 2020

## Virus Genome Detection SARS-CoV-2

### Interim Evaluation of Results

Submitted by 112 out of 484 Laboratories

(as of 14 April 2020, 01:57 pm Berlin time)

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<sup>2</sup>INSTAND e.V. - Gesellschaft zur Förderung der Qualitätssicherung  
in medizinischen Laboratorien e.V, Düsseldorf

<sup>3</sup>IQVD GmbH - Institut für Qualitätssicherung in der Virusdiagnostik

<sup>4</sup>GBD Gesellschaft für Biotechnologische Diagnostik mbH, Berlin

# Disclosure

Heinz Zeichhardt is share-holder  
of  
GBD Gesellschaft für Biotechnologische Diagnostik mbH, Berlin  
and  
IQVD GmbH - Institut für Qualitätssicherung in der Virusdiagnostik, Berlin

# EQA Network

## Scientific umbrella

German Association for Prevention of Virus Diseases (DVV e.V.)

Society of Virology (GfV e.V.)

German Society for Hygiene and Microbiology (DGHM e.V.)

## Partners

### Berlin

Teams of

GBD Gesellschaft für Biotechnologische Diagnostik mbH, Berlin

and

IQVD GmbH - Institut für Qualitätssicherung in der Virusdiagnostik, Berlin

and

### Düsseldorf

INSTAND-Team

and

38 INSTAND Expert Laboratories

incl.

Robert Koch-Institut

Paul-Ehrlich-Institut

National Reference and Consiliary Labs

and

**EMPIR**  
**AntiMicroResist**

**EMRP**  
European Metrology Research Programme  
Programme of EURAMET  
The EMRP is jointly funded by the EMRP participating countries within EURAMET and the European Union



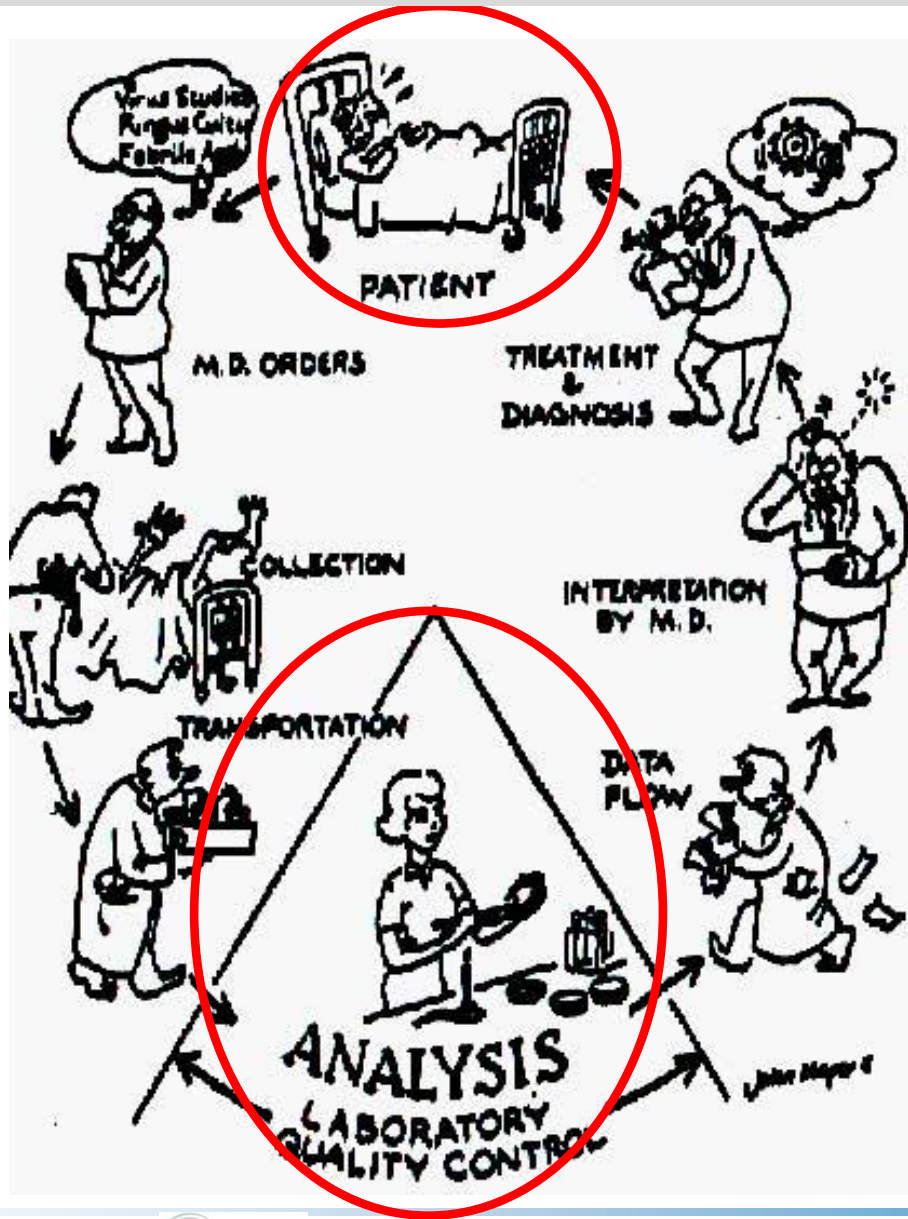
**JRC – Joint Research Centre (BE)**

 **LGC – National Measurement Laboratory (UK)**

**NIB – National Institute of Biology (SI)**

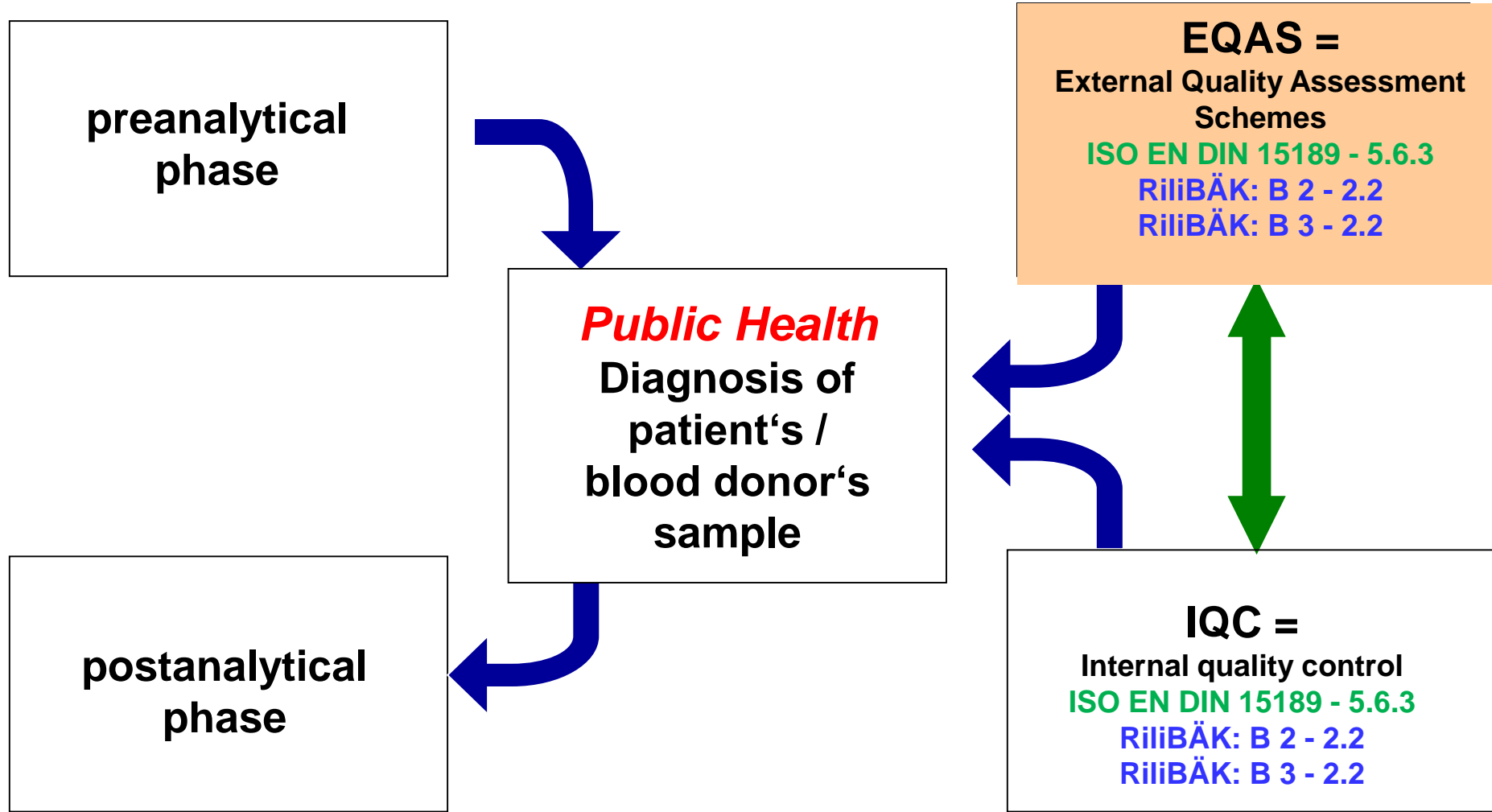
**PTB - Physikalisch-Technische Bundesanstalt (DE)**

# The Cycle of Laboratory Diagnosis

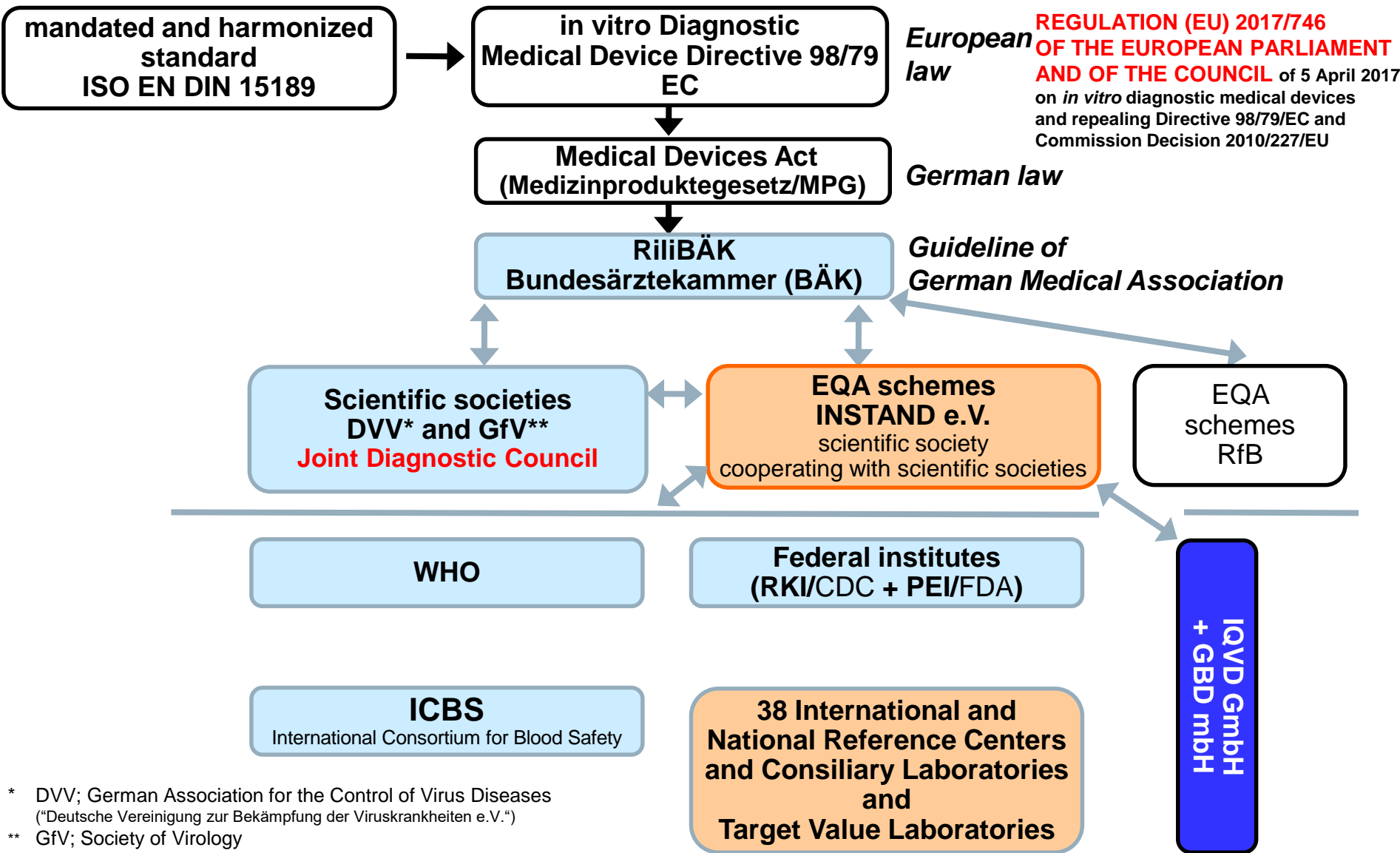


Quality Management  
in Medical Laboratories  
ISO 9000:2000  
Wemmie Elsenga  
[http://www.epbs.net/brussels/brussels03\\_elsenga.htm](http://www.epbs.net/brussels/brussels03_elsenga.htm)

# The Role of Quality Control for Public Health and Quality Improvement of Diagnostics and Blood Safety



# INSTAND e.V. - Quality Assurance in (Virus) Diagnostics



**REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL** of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

\* DVV; German Association for the Control of Virus Diseases ("Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V.")  
 \*\* GfV; Society of Virology ("Gesellschaft für Virologie e.V.")



# INSTAND e.V.

Gesellschaft zur Förderung der Qualitätssicherung  
in medizinischen Laboratorien e.V.

accredited by:



## INSTAND E.V. – A SCIENTIFIC SOCIETY COOPERATING WITH INTERNATIONAL AND NATIONAL SOCIETIES AND ORGANISATIONS

### International

14 Organisations / Scientific Societies

#### INTERNATIONAL

- Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS)
- EQAS/PT-Provider, QualiCont, Hungary
- European Committee for Standardization (CEN)
- European Organisation For External Quality Assurance Providers in Laboratory Medicine (EQALM)
- International Consortium for Blood Safety (ICBS)
- International Organisation for Standardisation (ISO)
- Joint Committee for Traceability in Laboratory Medicine (JCTLM)
- MQ Zürich Schweiz
- National Institute of Standards and Technology (NIST)
- Österreichische Gesellschaft für Qualitätssicherung und Standardisierung medizinisch-diagnostischer Untersuchungen (ÖQUASTA)
- Working Group HbA1c (IFCC)
- Working Group HbA2 (IFCC)
- World Association of Pathology and Laboratory Medicine (WASPaLM)
- World Health Organisation

- Deutsche Akkreditierungsstelle (DAkkS)
- Deutsche Dermatologische Gesellschaft e.V. (DDG)
- Deutsche Gesellschaft für Hämatologie und Onkologie e.V. (DGHO)
- Deutsche Gesellschaft für Hygiene und Mikrobiologie e.V. (DGHM)
- Deutsche Gesellschaft für Immungenetik e.V. (DGI)
- Deutsche Gesellschaft für Innere Medizin e.V. (DGIM)
- Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)
- Deutsche Gesellschaft für Liquordiagnostik und Klinische Neurochemie e.V. (DGLN)
- Deutsche Gesellschaft für Mineralstoffe und Spurenelemente e.V. (GMS)
- Deutsche Gesellschaft für Parasitologie e.V. (DGP)
- Deutsche Gesellschaft für Transfusionsmedizin und Immunhämatologie e.V. (DGTI)
- Deutsche Gesellschaft für Urologie e.V. (DGU)
- Deutsche Gesellschaft für Zytologie e.V. (DGZ)
- Deutsche Vereinigung zur Bekämpfung der Viruskrankheiten e.V. (DVV)
- Deutsche Vereinte Gesellschaft für Klinische Chemie und Laboratoriumsmedizin e.V. (DGKL)
- Deutschsprachige Mykologische Gesellschaft e.V. (DMykG)
- DIN - Deutsches Institut für Normung with special activities in „Normenausschuss Medizin“
- Gesellschaft für Thrombose und Hämostaseforschung e.V. (GTH)
- Gesellschaft für Virologie e.V. (GFV)
- National organisations for technical assistants and continuous education (dvta and diw-mta e.V.)
- Physikalisch-Technische Bundesanstalt (PTB)
- Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)

### National

28 Organisations / Scientific Societies

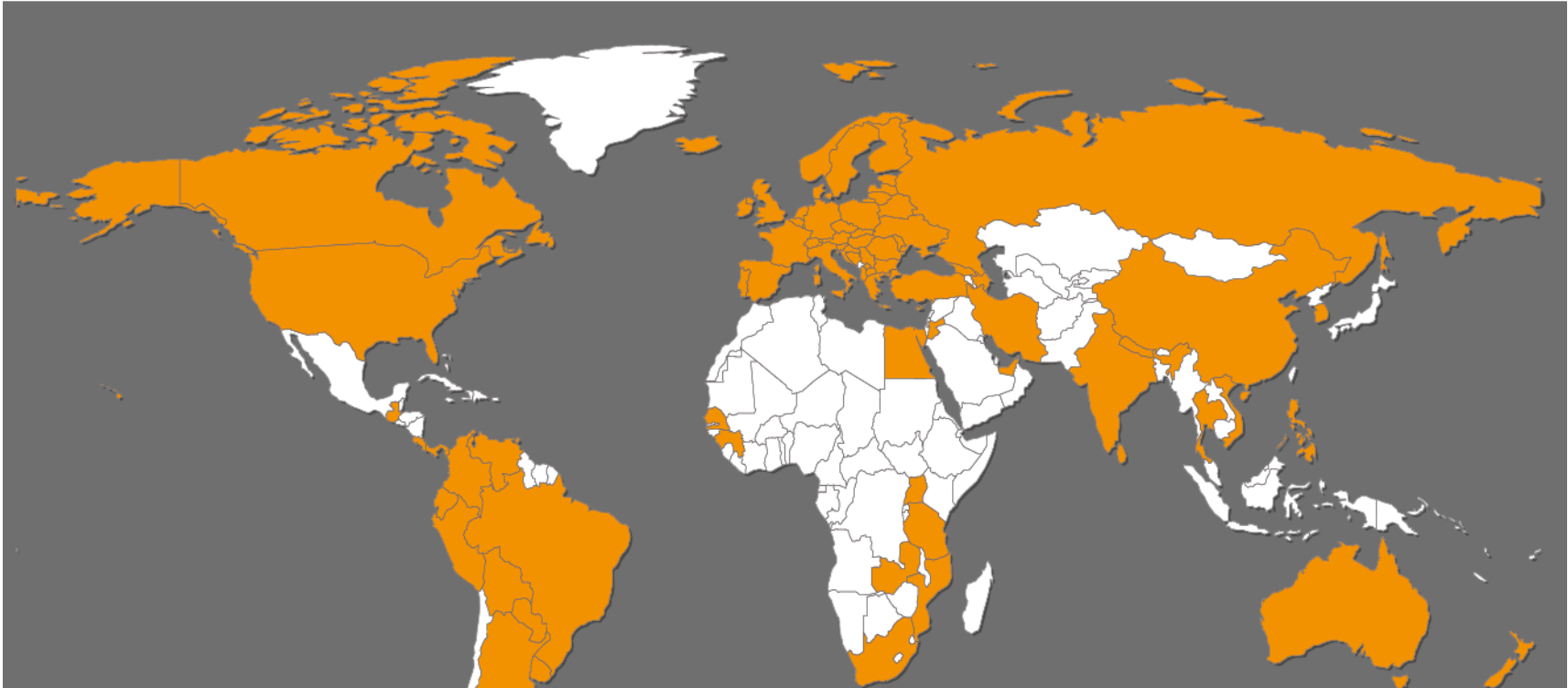
#### NATIONAL

- Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V. (AWMF)
- Arbeitsgruppe Therapeutisches Drug Monitoring (AGTDM) der Arbeitsgemeinschaft Neuropsychopharmakologie und Pharmakopsychiatrie e.V. (AGNP e.V.)
- Arbeitskreis Mykobakterien (AKM)
- Ärzteverband Deutscher Allergologen e.V. (AeDA)
- Berufsverband Deutscher Dermatologen e.V. (BVDD)
- Bundesärztekammer (BÄK, German Medical Association)



# INSTAND e.V.

## Cooperation with participants from more than 80 Countries



- Albania
- Argentina
- Australia
- Austria
- Azerbaijan
- Belarus
- Belgium
- Bolivia
- Bosnia and Herzegovina
- Brazil
- Bulgaria
- Canada
- China
- Colombia
- Costa Rica
- Croatia
- Cyprus
- Czech Republic
- Denmark
- Ecuador
- Egypt
- Estonia
- Finland
- France
- Georgia
- Germany
- Greece
- Guatemala
- Guinea
- Hungary
- Iceland
- India
- Iran
- Ireland
- Italy
- Jordan
- Kosovo
- Latvia
- Liechtenstein
- Liechtenstein
- Lithuania
- Luxembourg
- Macedonia
- Malta
- Moldova
- Mozambique
- Nepal
- Netherlands
- Netherlands Antilles
- New Zealand
- Norway
- Panama
- Paraguay
- Peru
- Philippines
- Poland
- Portugal
- Romania
- Russian Federation
- Samoa
- Senegal
- Serbia
- Singapore
- Slovakia
- Slovenia
- South Africa
- South Korea
- Spain
- Sri Lanka
- Sweden
- Switzerland
- Tanzania
- Thailand
- Trinidad
- Turkey
- Uganda
- Ukraine
- United Arab Emirates
- United Kingdom
- Uruguay
- US Minor Outlying Islands
- USA
- Venezuela
- Vietnam



# INSTAND e.V.

Immunohaematology  
(41)

Autoimmune diseases (57)

Haemostasis  
(54)

Haematology  
(54)

Clinical chemistry  
(43)

Trace elements  
(50)

Pharmaceuticals and drugs  
(152)

> 350

Programs

Virtual EQA schemes  
(3)

Virology  
(78)

Bacteriology / serology  
(47)

Bacterial genome detection  
(17)

Parasitology  
(8)

Mycology  
(7)

Molecular diagnostics  
(90)

POCT  
(34)

EQAS in virus diagnostics - 2019:

- > 1700 participating laboratories
- from > 60 countries worldwide

# INSTAND EQA Schemes (78 Schemes) in Virus Immunology and Genome Detection 2020

Serology and Antigen Detection		Virus Genome Detection and Typing	
HIV-1/2	Herpes simplex Viruses	HIV-1 (RNA) HIV-2 (RNA)	Measles Rubella Mumps Viruses
HIV-1 p24 Ag	Varicella Zoster Virus	HIV-1 Resistance + Tropism	Adenoviruses
HTLV-1/2	Epstein Barr Virus	Hepatitis A Virus	Norovirus Rotavirus
Hepatitis A Virus	Resp. Sync. Virus Ag	Hepatitis B Virus + Genotyping + Resistance	CoV incl. MERS CoV <b>SARS-CoV-2 NEW</b>
Hepatitis B Virus, Prg. I	Influenza A and B Ag + A/H1N1 pdm 2009 + A/H5N1+A/H7N9	Hepatitis C Virus + Genotyping + Resistance	Enteroviruses + Enterovirus (WHO/RKI) Parechovirus <b>NEW</b>
Hepatitis B Virus, Prg. II	Rubella Virus Measles Virus Mumps Virus	Hepatitis D Virus Hepatitis E Virus	Human Rhinoviruses Resp. Syncytial Virus Hum. Metapneumovirus Parainfluenza viruses
Hepatitis C Virus	TBE Virus	Torque Teno Virus <b>NEW</b>	Influenza A and B incl avian
Hepatitis D Virus	Hantavirus	Cytomegalovirus + Resistance	BK Virus JC Virus
Hepatitis E Virus	Dengue Virus Chikungunya Virus Zika Virus	Epstein-Barr Virus Herpes simplex Viruses HHV-6 <b>NEW</b> HHV-8 <b>NEW</b>	Dengue Virus West Nile Virus Chikungunya Virus Zika Virus
Parvovirus B19	Rabies Virus	Varicella Zoster Virus	Hum. Papilloma Viruses
Cytomegalovirus	Borna Virus <b>NEW</b>	Parvovirus B19	Rabies Virus
<b>SARS-CoV-2 NEW</b>	BSE (PrPsc) (2002-2007)	Multiplex: Respiratory Viruses (2 programs)	Multiplex: <b>NEW</b> Viral Meningitis/Encephalitis
		Multiplex: Gastrointestinal Viruses	Borna Viruses <b>NEW</b>

# Extra INSTAND EQA Scheme (340) - April 2020

## Virus Genome Detection SARS-CoV-2

### Cooperation partner

National Consultant Laboratory for Coronaviruses

Institute of Virology, Charité – University Medicine Berlin, Campus Charité Mitte

Prof. Dr. Christian Drosten

Dr. Victor M. Corman

Dr. Daniela Niemeyer

### Expert Laboratories

Universitätsklinikum Frankfurt,  
Institut für Medizinische Virologie

Prof. Dr. Sandra Ciesek

Prof. Dr. Holger F. Rabenau

Prof. Dr. Annemarie Berger

Uniklinik Köln, Institut für Virologie

Nationales Referenzzentrum für

Papillom- und Polyomaviren

Prof. Dr. Florian Klein

Prof. Dr. Ulrike Wieland

Dr. Steffi Silling

Dr. Rolf Kaiser

Dr. Eva Heger

Dr. Elena Knops

Medizinisches Infektiologiezentrum

Berlin

Dr. M. Obermeier

Dr. R. Ehret

# Interim Evaluation

## Based on the Results of 112 out of 484 Laboratories

Reported by 14 April 2020 01:57 pm Berlin Time







Sample no.	Sample property
340059	SARS-CoV-2 / 1 : 1 000 diluted <sup>\$</sup>
340060	CoV OC43 / 1 : 2 500 diluted / specificity control
340061	???
340062	???
340063	???
340064	SARS-CoV-2 / 1 : 100 000 diluted <sup>\$</sup>
340065	???

<sup>\$</sup> The SARS-CoV-2 positive samples 340059 and 340064 represent different dilution steps from a dilution series of a lysate from cells, infected with SARS-CoV-2 (inactivated).

# Interim Evaluation

## Based on the Results of 112 out of 484 Laboratories

Reported by 14 April 2020 01:57 pm Berlin Time

Sample No.	Sample properties	Expected qualitative result for SARS-CoV-2	Gene region	Correct results per reported results differentiated by gene region	Reported Ct/Cp-results differentiated by gene region median (min – max)
Sample 340059	SARS-CoV-2 1 : 1 000 diluted <sup>§</sup> 	positive	E	83/83 (100%)	22.3 (17.7-29.4)
			N	22/22 (100%)	22.9 (17.9-30.9)
			ORF1a	7/7 (100%)	22.8 (21.7-28.7)
			ORF1ab	1/1 (100%)	20.9 (20.9-20.9)
			RdRP	41/41 (100%)	23.5 (20.5-34.4)
			S	27/27 (100%)	21.7 (18.0-24.8)
			n.s. <sup>§</sup>	29/29 (100%)	22.2 (10.4-33.0)
		<b>total</b>	 <b>210/210 (100%)</b>	 <b>22.6</b>	
Sample 340064	SARS-CoV-2 1 : 100 000 diluted <sup>§</sup> 	positive	E	83/83 (100%)	29.1 (24.1-33.5)
			N	22/22 (100%)	29.6 (26.2-37.5)
			ORF1a	7/7 (100%)	28.7 (28.0-30.3)
			ORF1ab	1/1 (100%)	29.6 (29.6-29.6)
			RdRP	41/41 (100%)	30.4 (26.9-41.4)
			S	27/27 (100%)	28.6 (25.0-31.5)
			n.s. <sup>§</sup>	29/29 (100%)	29.3 (16.0-40.0)
		<b>total</b>	 <b>210/210 (100%)</b>	 <b>29.4</b>	
Sample 340060	CoV OC43 1 : 2 500 diluted specificity control*	negative	E	78/83 (94.0%)	-
			N	19/21 (90.5%) <sup>#</sup>	-
			ORF1a	7/7 (100%)	-
			ORF1ab	1/1 (100%)	-
			RdRP	36/39 (92.3%) <sup>#</sup>	-
			S	27/27 (100%)	-
			n.s. <sup>§</sup>	29/29 (100%)	-
		<b>total</b>	<b>197/210 (93.8%)<sup>#</sup></b>	-	

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## Based on the Results of 112 out of 484 Laboratories

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Sample No.	Sample properties	Expected qualitative result for SARS-CoV-2	Gene region	Correct results per reported results differentiated by gene region	Reported Ct/Cp-results differentiated by gene region median (min – max)
Sample 340059	SARS-CoV-2 1 : 1 000 diluted <sup>§</sup>	positive	E	83/83 (100%)	22.3 (17.7-29.4)
			N	22/22 (100%)	22.9 (17.9-30.9)
			ORF1a	7/7 (100%)	22.8 (21.7-28.7)
			ORF1ab	1/1 (100%)	20.9 (20.9-20.9)
			RdRP	41/41 (100%)	23.5 (20.5-34.4)
			S	27/27 (100%)	21.7 (18.0-24.8)
			n.s. <sup>§</sup>	29/29 (100%)	22.2 (10.4-33.0)
		<b>total</b>	<b>210/210 (100%)</b>	<b>22.6</b>	
Sample 340064	SARS-CoV-2 1 : 100 000 diluted <sup>§</sup>	positive	E	83/83 (100%)	29.1 (24.1-33.5)
			N	22/22 (100%)	29.6 (26.2-37.5)
			ORF1a	7/7 (100%)	28.7 (28.0-30.3)
			ORF1ab	1/1 (100%)	29.6 (29.6-29.6)
			RdRP	41/41 (100%)	30.4 (26.9-41.4)
			S	27/27 (100%)	28.6 (25.0-31.5)
			n.s. <sup>§</sup>	29/29 (100%)	29.3 (16.0-40.0)
		<b>total</b>	<b>210/210 (100%)</b>	<b>29.4</b>	
Sample 340060	CoV OC43 1 : 2 500 diluted specificity control*	negative	E	78/83 (94.0%)	-
			N	19/21 (90.5%) <sup>#</sup>	-
			ORF1a	7/7 (100%)	-
			ORF1ab	1/1 (100%)	-
			RdRP	36/39 (92.3%) <sup>#</sup>	-
			S	27/27 (100%)	-
			n.s. <sup>§</sup>	29/29 (100%)	-
		<b>total</b>	<b>197/210 (93.8%)<sup>#</sup></b>	<b>-</b>	

# Interim Evaluation

## Based on the Results of 112 out of 484 Laboratories

Reported by 14 April 2020 01:57 pm Berlin Time

Sample: 340064 – SARS-CoV-2 positive (inactivated), 1 : 100 000 diluted

Reagent	Testkit	Total (N=210)	positive (N=210)	Quota (100%)	Ct/Cp Median	Ct/Cp Min	Ct/Cp Max
<b>E-Gene</b>							
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	14	14	100,00%	29.1	26.5	32.5
OTHER MANUFACTURERS		2	2	100,00%			
IN HOUSE		7	7	100,00%	30.1	27.6	33.5
ELITech	GeneFinder COVID-19 Plus	2	2	100,00%	28.1	26.9	29.2
EURO IMMUN	EURORealTime SARS-CoV-2	1	1	100,00%	30.2	30.2	30.2
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	1	1	100,00%			
Priv. Inst. f. Immunol. u. Mol.genetik	AmpliGnost CoV-2 E-Gen	3	3	100,00%	26.2	25.5	29.5
QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel	2	2	100,00%	30.9	30.8	30.9
R-BIOPHARM	RIDA GENE SARS-CoV-2 RUO	10	10	100,00%	29.7	24.1	32.8
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	13	13	100,00%	29.0	28.5	32.0
SEEGENE	Allplex 2019 n-CoV Assay	9	9	100,00%	27.9	26.7	30.7
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV E-gene	19	19	100,00%	29.4	27.3	31.5
		<b>83</b>	<b>83</b>	<b>100,00%</b>	<b>29.05</b>	<b>24.1</b>	<b>33.5</b>
<b>N-Gene</b>							
OTHER MANUFACTURERS		3	3	100,00%	26.2	26.2	26.2
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	1	1	100,00%	26.3	26.3	26.3
IN HOUSE		2	2	100,00%	29.1	28.0	30.1
ELITech	GeneFinder COVID-19 Plus	2	2	100,00%	27.9	26.2	29.5
EURO IMMUN	EURORealTime SARS-CoV-2	1	1	100,00%	27.8	27.8	27.8
PATHOFINDER	RealAccurate Quadruplex Corona-plus PCR Kit	1	1	100,00%	31.4	31.4	31.4
SEEGENE	Allplex 2019 n-CoV Assay	9	9	100,00%	29.6	28.9	31.4
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV N-gene	3	3	100,00%	37.3	35.0	37.5
		<b>22</b>	<b>22</b>	<b>100,00%</b>	<b>29.6</b>	<b>26.2</b>	<b>37.5</b>
<b>ORF1a</b>							
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	1	1	100,00%			
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	6	6	100,00%	28.7	28.0	30.3
		<b>7</b>	<b>7</b>	<b>100,00%</b>	<b>28.7</b>	<b>28.0</b>	<b>30.3</b>
<b>ORF1ab</b>							
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	1	1	100,00%	29.6	29.6	29.6
		<b>1</b>	<b>1</b>	<b>100,00%</b>	<b>29.6</b>	<b>29.6</b>	<b>29.6</b>



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<b>E-Gene</b>							
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	14	14	100,00%	29.1	26.5	32.5
OTHER MANUFACTURERS		2	2	100,00%			
IN HOUSE		7	7	100,00%	30.1	27.6	33.5
ELITech	GeneFinder COVID-19 Plus	2	2	100,00%	28.1	26.9	29.2
EURO IMMUN	EURORealTime SARS-CoV-2	1	1	100,00%	30.2	30.2	30.2
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	1	1	100,00%			
Priv. Inst. f. Immunol. u. Mol.genetik	AmpliGnost CoV-2 E-Gen	3	3	100,00%	26.2	25.5	29.5
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		<b>83</b>	<b>83</b>	<b>100,00%</b>	<b>29.05</b>	<b>24.1</b>	<b>33.5</b>
<b>N-Gene</b>							
OTHER MANUFACTURERS		3	3	100,00%	26.2	26.2	26.2
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	1	1	100,00%	26.3	26.3	26.3
IN HOUSE		2	2	100,00%	29.1	28.0	30.1
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		<b>22</b>	<b>22</b>	<b>100,00%</b>	<b>29.6</b>	<b>26.2</b>	<b>37.5</b>
<b>ORF1a</b>							
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	1	1	100,00%			
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	6	6	100,00%	28.7	28.0	30.3
		<b>7</b>	<b>7</b>	<b>100,00%</b>	<b>28.7</b>	<b>28.0</b>	<b>30.3</b>
<b>ORF1ab</b>							
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	1	1	100,00%	29.6	29.6	29.6
		<b>1</b>	<b>1</b>	<b>100,00%</b>	<b>29.6</b>	<b>29.6</b>	<b>29.6</b>

# Interim Evaluation

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IN HOUSE		7	7	100,00%	30.1	27.6	33.5
ELITech	GeneFinder COVID-19 Plus	2	2	100,00%	28.1	26.9	29.2
EURO IMMUN	EURORealTime SARS-CoV-2	1	1	100,00%	30.2	30.2	30.2
MIKROGEN	ampliCube Coronavirus SARS-CoV-2 RUO	1	1	100,00%			
Priv. Inst. f. Immunol. u. Mol.genetik	AmpliGnost CoV-2 E-Gen	3	3	100,00%	26.2	25.5	29.5
QIAGEN	QIAstat-Dx Respiratory 2019-nCoV Panel	2	2	100,00%	30.9	30.8	30.9
R-BIOPHARM	RIDA GENE SARS-CoV-2 RUO	10	10	100,00%	29.7	24.1	32.8
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	13	13	100,00%	29.0	28.5	32.0
SEEGENE	Allplex 2019 n-CoV Assay	9	9	100,00%	27.9	26.7	30.7
TIB MOLBIOL	LightMix Modular SARS and Wuhan CoV E-gene	19	19	100,00%	29.4	27.3	31.5
		<b>83</b>	<b>83</b>	<b>100,00%</b>	<b>29.05</b>	<b>24.1</b>	<b>33.5</b>

# Interim Evaluation

## Based on the Results of 112 out of 484 Laboratories

Reported by 14 April 2020 01:57 pm Berlin Time

**Sample: 340064 – SARS-CoV-2 positive (inactivated), 1 : 100 000 diluted**

Reagent	Testkit	Total (N=210)	positive (N=210)	Quota (100%)	Ct/Cp Median	Ct/Cp Min	Ct/Cp Max
 <b>RdRP-Gene</b>							
OTHER MANUFACTURERS		4	4	100,00%	33.5	28.5	38.5
IN HOUSE		6	6	100,00%	29.0	26.9	34.3
ELITech	GeneFinder COVID-19 Plus	3	3	100,00%	30.4	30.4	30.8
SEEGENE	Allplex 2019 n-CoV Assay	13	13	100,00%	29.6	28.2	32.4
TIB MOLBIOL	LightMix Modular Wuhan CoV RdRP-gene	15	15	100,00%	33.5	29.5	41.4
		<b>41</b>	<b>41</b>	<b>100,00%</b>	<b>30.4</b>	<b>26.9</b>	<b>41.4</b>
 <b>S-Gene</b>							
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	20	20	100,00%	28.3	25.0	31.5
OTHER MANUFACTURERS		1	1	100,00%			
APPLIED BIOSYSTEMS	TaqMan 2019-nCoV Assay Kit v1	1	1	100,00%	26.9	26.9	26.9
CERTEST BIOTEC	VIASURE SARS-CoV-2 S gene	5	5	100,00%	31.1	30.7	31.2
		<b>27</b>	<b>27</b>	<b>100,00%</b>	<b>28.6</b>	<b>25.0</b>	<b>31.5</b>
 <b>gene region not specified by participants</b>							
ABBOTT	RealTime SARS-CoV-2	1	1	100,00%	16.0	16.0	16.0
ALTONA DIAGNOSTIC	RealStar SARS-CoV-2 RT-PCR Kit 1.0	1	1	100,00%	31.0	31.0	31.0
OTHER MANUFACTURERS		9	9	100,00%	30.8	27.8	34.7
BOSCH HEALTHCARE SOLUTIONS	Vivalytic VRI Multiplex Test	1	1	100,00%			
IN HOUSE		2	2	100,00%	25.5	25.5	25.5
FAST-TRACK DIAGNOSTICS	FTD SARS-CoV-2 assay	1	1	100,00%	28.7	28.7	28.7
GENEPROOF	SARS-CoV-2 PCR Kit	1	1	100,00%	25.4	25.4	25.4
GENESIG	Coronavirus COVID-19	3	3	100,00%	34.9	34.2	40.0
LUMINEX	NxTAG CoV	1	1	100,00%			
ROCHE DIAGNOSTICS	COBAS SARS-CoV-2 Test	5	5	100,00%	28.4	28.0	31.9
SEEGENE	Allplex 2019 n-CoV Assay	4	4	100,00%	30.2	28.0	31.1
		<b>29</b>	<b>29</b>	<b>100,00%</b>	<b>29.3</b>	<b>16.0</b>	<b>40.0</b>

# Interim Evaluation

## Based on the Results of 112 out of 484 Laboratories

Reported by 14 April 2020 01:57 pm Berlin Time

Sample No.	Sample properties	Expected qualitative result for SARS-CoV-2	Gene region	Correct results per reported results differentiated by gene region	Reported Ct/Cp-results differentiated by gene region median (min – max)
Sample 340059	SARS-CoV-2 1 : 1 000 diluted <sup>§</sup>	positive	E	83/83 (100%)	22.3 (17.7-29.4)
			N	22/22 (100%)	22.9 (17.9-30.9)
			ORF1a	7/7 (100%)	22.8 (21.7-28.7)
			ORF1ab	1/1 (100%)	20.9 (20.9-20.9)
			RdRP	41/41 (100%)	23.5 (20.5-34.4)
			S	27/27 (100%)	21.7 (18.0-24.8)
			n.s. <sup>§</sup>	29/29 (100%)	22.2 (10.4-33.0)
		<b>total</b>	<b>210/210 (100%)</b>	<b>22.6</b>	
Sample 340064	SARS-CoV-2 1 : 100 000 diluted <sup>§</sup>	positive	E	83/83 (100%)	29.1 (24.1-33.5)
			N	22/22 (100%)	29.6 (26.2-37.5)
			ORF1a	7/7 (100%)	28.7 (28.0-30.3)
			ORF1ab	1/1 (100%)	29.6 (29.6-29.6)
			RdRP	41/41 (100%)	30.4 (26.9-41.4)
			S	27/27 (100%)	28.6 (25.0-31.5)
			n.s. <sup>§</sup>	29/29 (100%)	29.3 (16.0-40.0)
		<b>total</b>	<b>210/210 (100%)</b>	<b>29.4</b>	
Sample 340060	CoV OC43 1 : 2 500 diluted specificity control*	negative	E	78/83 (94.0%)	-
			N	19/21 (90.5%) <sup>#</sup>	-
			ORF1a	7/7 (100%)	-
			ORF1ab	1/1 (100%)	-
			RdRP	36/39 (92.3%) <sup>#</sup>	-
			S	27/27 (100%)	-
			n.s. <sup>§</sup>	29/29 (100%)	-
		<b>total</b>	<b>197/210 (93.8%)<sup>#</sup></b>	<b>-</b>	

# Thank you very much!

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